

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alan Bruce Montgomery *et al.*

Confirmation No.: 4624

Serial No.: 10/613,639

Group Art Unit: 1616

Filing Date: July 3, 2003

Examiner: James Henry Alstrum-Acevedo

Patent No.: 7,214,364

Issue Date: May 8, 2007

For: INHALABLE AZTREONAM LYSINATE FORMULATION FOR TREATMENT  
AND PREVENTION OF PULMONARY BACTERIAL INFECTIONS

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Certificate of Corrections Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22314-1450

**REQUEST FOR CERTIFICATE OF CORRECTION  
UNDER 37 C.F.R. § 1.323**

The patentee of the above-identified patent, through its attorney, hereby petitions for issuance of a Certificate of Correction in the above-identified patent. A completed Certificate of Correction Form PTO/SB/44 is enclosed herein.

**In the Specification** begins on page 2 of this paper.

**In the Claims** begins on page 4 of this paper.

**Remarks** begin on page 5 of this paper.

**IN THE SPECIFICATION:**

At column 5, line 26, delete “lysinate”.

At column 6, line 54, delete “lysinate”.

At column 13, line 55, insert -- of aztreonam-- between “mg/mL” and “,”.

At column 13, line 56, insert -- of aztreonam-- between “mg/mL” and “,”.

At column 16, line 42, delete “lysinate”.

At column 16, line 49, delete “lysinate”.

At column 16, line 60, delete “lysinate”.

At column 16, line 61, delete “lysinate”.

At column 17, line 2, delete “lysinate”.

At column 36, line 24, delete “lysinate”.

At column 37, line 40, after the word “solution”, delete “of” and insert therefor “containing”.

At column 37, line 40, insert -- of aztreonam-- after “mg/ml”.

At column 37, line 41, after the word “solution”, delete “of” and insert therefor “containing”.

At column 37, line 41, insert -- of aztreonam-- after “mg/ml”.

At column 37, line 42, after the word “solution”, delete “of” and insert therefor  
“containing”.

At column 37, line 42, insert -- of aztreonam-- after “mg/ml”.

**IN THE CLAIMS:**

At column 40, line 47, i.e., the 6<sup>th</sup> line of Claim 1, after the term “about 1 to about”, delete “5μ” and insert therefor --5μm--.

At column 40, line 60, i.e., the third line of Claim 7, delete the term “may be” and insert therefor --is--.

At column 40, line 60, i.e., the third line of Claim 7, after the word “as”, delete “the” and insert therefor --an--.

At column 40, line 61, i.e., the 4<sup>th</sup> line of Claim 7, after the word “as”, delete “a” and insert therefor --an aerosolable--.

At column 40, line 62, i.e., the 5<sup>th</sup> line of Claim 7, delete “the aerosolable solution”.

At column 40, line 63, i.e., the first line of Claim 8, insert --mg-- between “10 to 100” and “of”.

At column 40, line 65, i.e., the first line of Claim 9, after the word “claim”, delete “7” and insert therefor “8”.

At column 40, line 66, i.e., the second line of Claim 9, delete “lysinate”.

At column 41, line 14, i.e., the 4<sup>th</sup> line of Claim 13, insert --sodium-- between “of” and “chloride”.

At column 42, line 6, i.e., the second line of Claim 15, delete “lysinate”.

**REMARKS**

Errors of a clerical or typographical nature, or of minor character, which occurred through the fault of patentee, appear in the above-identified patent. Patentee respectfully submits that such errors occurred in good faith and without deceptive intent.

In the specification, the word "lysinate" has been mistakenly added and should be deleted at the following places: column 5, line 26; column 6, line 54; column 16, line 42; column 16, line 49; column 16, line 60; column 16, line 61; column 17, line 2; and column 36, line 24.

In the specification, the term "of aztreonam" has been mistakenly omitted and should be inserted between "mg/mL" and "," at column 13, line 55, and between "mg/mL" and "," at column 13, line 56.

In the specification, there are minor errors in the three sentences at column 37, lines 40 to 42. Specifically, at column 37, line 40, the word "of" after "solution" should be replaced "having" and the term "of aztreonam" should be added after "mg/ml". The two sentences at column 37, lines 41 and 42 should be corrected in the similar fashion. Thus, the three sentences at column 37, lines 40 to 42 should read as follows:

- "1. 1.0 ml of aztreonam lysinate solution ~~of~~containing 75 mg/ml of aztreonam
  2. 2.0 ml of aztreonam lysinate solution ~~of~~containing 75 mg/ml of aztreonam
  3. 3.0 ml of aztreonam lysinate solution ~~of~~containing 75 mg/ml of aztreonam"
- (strikethrough and underline added to indicate the correct sentence)

Support for the above corrections can be found in the specification at least at column 14, lines 26 to 29; column 16, lines 56 to 57; column 16, lines 62 to 64; column 17, lines 10 to 15; column 20, lines 20 to 25; and column 32, lines 19 to 23. Specifically, the specification states that a dose of aztreonam lysinate is formulated in, most preferably, about 75 mg of aztreonam per mL (see column 14, lines 26 to 29). The specification also describes two exemplary aerosolable aztreonam lysinate formulations with 75 mg/mL and 90 mg/mL of aztreonam, respectively (see column 16, lines 62 to 64, and column 17, lines 10 to 15). Furthermore, the specification states that dose of aztreonam is recalculated to refer only to an aztreonam component (see column 16, lines 56 to 57). In addition, the specification provides an exemplary formulation package in which each 1 mL vial contains 75 mg of aztreonam and 47 mg of lysine as aztreonam lysinate (see column 20, lines 20 to 25). Patentee respectfully submits that the

above errors in the specification are of clerical or typographical nature, or of minor character, and occurred without deceptive intent.

In the claims, at column 40, line 47, i.e., the 6<sup>th</sup> line of Claim 1, a letter “m” has been mistakenly omitted from the term “5μ” and should be inserted. Thus, the term “5μ” at the 6<sup>th</sup> line of Claim 1 should read “5μm”. Support for “5μm” can be found throughout the specification, and the specific support can be found at least in the specification at column 18, line 12; column 19, line 17; column 23, line 64; column 27, line 4; and column 35, lines 6 and 33, wherein the term “5 microns” is recited. According to the Merriam-Webster's Collegiate Dictionary, 10th Edition, “micron” is synonymous with “micrometer”, which means a unit of length equal to one millionth of a meter, i.e., μm. Patentee respectfully submits that these errors are clerical or typographical and occurred without deceptive intent.

In the claims, there are minor errors in Claim 7 at column 40, lines 60 to 62. Claim 7 should read as follows:

“7. The composition of claim 1 comprising from about 1 to 250 mg of the aztreonam lysinate, wherein the composition ~~may be~~ is administered as ~~the an inhalable dry powder~~ by a dry powder inhaler or as ~~a an aerosolable~~ an aerosolable diluted saline solution by a metered dose inhaler ~~the aerosolable solution.~~”  
(strikethrough and underline added to indicate the correct sentence)

Support for the corrections can be found in the specification at least at column 4, lines 63 to 66; column 5, lines 20 to 23; and column 16, lines 38 to 57. Patentee respectfully submits that these errors occurred without deceptive intent.

In the claims, at column 40, line 63, i.e., the first line of Claim 8, the term “mg” between “10 to 100” and “of” has been mistakenly omitted and should be inserted. The term “mg” is used throughout the specification to describe the weight amount of aztreonam or aztreonam lysinate. Specific support for “10 to 100 mg” can be found in the specification at least at column 18, lines 8 and 9; and column 27, line 3. Patentee respectfully submits that this error occurred without deceptive intent.

In the claims, at column 40, line 65, i.e., the first line of Claim 9, after the word “claim”, the number “7” should be “8”. Patentee respectfully submits that this error is of a typographical nature and occurred without deceptive intent.

In the claims, at column 41, line 14, i.e., the 4<sup>th</sup> line of Claim 13, the word “sodium” between “of” and “chloride” has been mistakenly omitted and should be inserted. Support for

this correction can be found throughout the specification, and specific support can be found at least at column 6, lines 16 to 27, wherein “sodium chloride” is presented as its chemical formula “NaCl”. Patentee respectfully submits that this error occurred without deceptive intent.

In the claims, the word “lysinate” has been mistakenly added to and should be deleted from the following places: column 40, line 66, i.e., the second line of Claim 9; and column 42, line 6, i.e., the second line of Claim 15. Support for the corrections can be found in the specification at least at column 14, lines 26 to 29; column 16, lines 56 to 57; column 16, lines 62 to 64; column 17, lines 10 to 15; column 20, lines 20 to 25; and column 32, lines 19 to 23. Specifically, the specification states that a dose of aztreonam lysinate is formulated in, most preferably, about 75 mg of aztreonam per mL (see column 14, lines 26 to 29). The specification also describes two exemplary aerosolable aztreonam lysinate formulations with 75 mg/mL and 90 mg/mL of aztreonam, respectively (see column 16, lines 62 to 64, and column 17, lines 10 to 15). Furthermore, the specification states that dose of aztreonam is recalculated to refer only to an aztreonam component (see column 16, lines 56 to 57). In addition, the specification provides an exemplary formulation package in which each 1 mL vial contains 75 mg of aztreonam and 47 mg of lysine as aztreonam lysinate (see column 20, lines 20 to 25). Patentee respectfully submits that these errors are of clerical or typographical nature, or of minor character, and occurred without deceptive intent.

Patentee believes that the above errors are of such a nature as to justify the issuance of a Certificate of Correction, and the correction of these errors does not involve such changes in the present patent as would constitute new matter or would require reexamination. Patentee has enclosed a completed Certificate of Correction Form PTO/SB/44. It is respectfully requested that a Certificate of Correction be issued to correct the errors in the present patent.


Because this Certificate of Correction relates to Applicant/Patentee's mistake, the Commissioner is hereby authorized to charge the fee set forth in 37 C.F.R. § 1.20(a) to Deposit Account No. 50-0310.

Dated: February 25, 2008

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Respectfully submitted,  
**COOLEY GODWARD KRONISH LLP**

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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

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PATENT NO. : 7,214,364 B2  
APPLICATION NO. : 10/613,639  
ISSUE DATE : May 8, 2007  
INVENTOR : Alan Bruce Montgomery

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

### IN THE SPECIFICATION

At column 5, line 26, delete "lysinate".

At column 6, line 54, delete "lysinate".

At column 13, line 55, insert -- of aztreonam-- between "mg/mL" and ",".

At column 13, line 56, insert -- of aztreonam-- between "mg/mL" and ",".

At column 16, line 42, delete "lysinate".

At column 16, line 49, delete "lysinate".

At column 16, line 60, delete "lysinate".

At column 16, line 61, delete "lysinate".

At column 17, line 2, delete "lysinate".

At column 36, line 24, delete "lysinate".

At column 37, line 40, after the word "solution", delete "of" and insert therefor "containing".

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.  
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At column 37, line 40, insert -- of aztreonam-- after "mg/ml".  
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At column 37, line 41, insert -- of aztreonam-- after "mg/ml".  
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At column 37, line 42, insert -- of aztreonam-- after "mg/ml".

### IN THE CLAIMS

At column 40, line 47, i.e., the 6<sup>th</sup> line of Claim 1, "5 $\mu$ " should read --5 $\mu$ m--.  
At column 40, line 60, i.e., the third line of Claim 7, "may be" should read --is--.  
At column 40, line 60, i.e., the third line of Claim 7, "the" should read --an--.  
At column 40, line 61, i.e., the 4<sup>th</sup> line of Claim 7, after the word "as", "a" should read --an aerosolable--.  
At column 40, line 62, i.e., the 5<sup>th</sup> line of Claim 7, delete "the aerosolable solution".

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